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ORIGINAL ARTICLE

Coaching Patients With Early Rheumatoid Arthritis to Healthy Physical Activity: A Multicenter, Randomized, Controlled Study

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Objective. **To investigate the effect of a 1-year coaching program for healthy physical activity on perceived health status, body function, and activity limitation in patients with early rheumatoid arthritis.**

Methods. **A total of 228 patients (169 women, 59 men, mean age 55 years, mean time since diagnosis 21 months) were randomized to 2 groups after assessments with the EuroQol visual analog scale (VAS), Grippit, Timed-Stands Test, Escola Paulista de Medicina Range of Motion scale, walking in a figure-of-8, a visual analog scale for pain, the Health Assessment Questionnaire disability index, a self-reported physical activity questionnaire, and the Disease Activity Score in 28 joints. All patients were regularly seen by rheumatologists and underwent rehabilitation as prescribed. Those in the intervention group were further individually coached by a physical therapist to reach or maintain healthy physical activity (≥30 minutes, moderately intensive activity, most days of the week).**

Results. **The retention rates after 1 year were 82% in the intervention group and 85% in the control group. The percentages of individuals in the intervention and control groups fulfilling the requirements for healthy physical activity were similar before (47% versus 51%; $P > 0.05$) and after (54% versus 44%; $P > 0.05$) the intervention. Analyses of outcome variables indicated improvements in the intervention group over the control group in the EuroQol VAS ($P = 0.025$) and muscle strength (Timed-Stands Test; $P = 0.000$) (Grippit; $P = 0.003$), but not in any other variables assessed.**

Conclusion. **A 1-year coaching program for healthy physical activity resulted in improved perceived health status and muscle strength, but the mechanisms remain unclear, as self-reported physical activity at healthy level did not change.**

INTRODUCTION

Rheumatoid arthritis (RA) has a major effect on perceived health, and an improved feeling of general wellness has been identified as an important target for the treatment of this condition (1). The unpredictable course of RA, symptoms such as pain and fatigue, reduced body functions, and limitations related to activity and participation may contribute to poor health perception. Extensive scientific evidence links physical activity to health benefits in the general population as well as in several subpopulations (2–6).

Planned and structured exercise confers benefits at low risk in a majority of patients with RA (7–9). Described outcomes relate mainly to body functions such as muscle strength and endurance, aerobic fitness, and joint range of motion. Pain reduction has also been reported, while findings related to reduced activity limitation and perceived health are still scarce (7,8,10). Exercise studies involving patients with RA have been performed mainly in clinical environments with physical therapists supervising their patients' exercise 2–3 times a week. Considering the restricted resources in health care, a shift toward community-based programs with the main focus on physical activity in everyday life has been proposed for future intervention studies (10). This is also in line with the preferences of individuals with RA who want physical activity integrated into their daily lives (11).

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In a progressive disease such as RA, interventions should aim at maintaining the behavior among those already physically active and increasing physical activity among the inactive. Such interventions, although community based, may still require some type of coaching, because individuals with RA may perceive pain, fatigue, and fear of aggravating their disease as potential barriers to physical activity (12). Coaching is pragmatically defined in the present study as structured counseling, goal setting, instruction, and continuous physical evaluation with feedback, rather than being based on one single existing behavior theory or model (13).

Healthy physical activity is defined here as ≥30 minutes of moderately intensive activity most days of the week. This is recommended to every adult in order to maintain physical and mental health in a broad sense and to reduce the risk of morbidity and premature death. These recommendations have also been adopted for patients with RA (14). Physical inactivity is a major public health problem in the Western world and people with arthritis are no exception (15). Rather, regardless of disability, individuals with arthritis have substantially lower rates of leisure-time physical activity than those without arthritis (16). Healthy physical activity and good lower-extremity function have recently been identified as predictors of general well-being in a descriptive prospective study over a 1-year period (17). An Internet-based physical activity intervention has recently indicated promising results as to improving physical activity behavior in patients with RA (18). However, as of yet there is no randomized controlled clinical trial to support the contention that physical activity intervention in patients with RA improves perceived health, body function, or activity limitation.

The aim of this study was to investigate the effect of a 1-year coaching program for healthy physical activity on perceived health status, body function, and activity limitation in patients with early RA.

MATERIALS AND METHODS

Study design. The detailed protocol for this multicenter, prospective, randomized, controlled study is available at http://www.controlled-trials.com/ISRCTN88886304/, and the study design is described in Figure 1. Briefly, assessments were made at study start (preintervention) and directly after the 1-year intervention (postintervention). Outcomes and potential confounding factors were assessed by rheumatologists and physical therapists using clinical examinations, questionnaires, and rating scales. Rheumatologists assessed disease activity (19) at regular outpatient visits. Physical therapists assessed perceived health status, body functions (muscle function, joint range of motion, and balance), and self-reported physical activity. The physical therapists were initially trained in the standardized use of the assessment methods. They were provided with written manuals and forms for the assessment procedures and were invited to regular recall sessions during the entire data collection period.

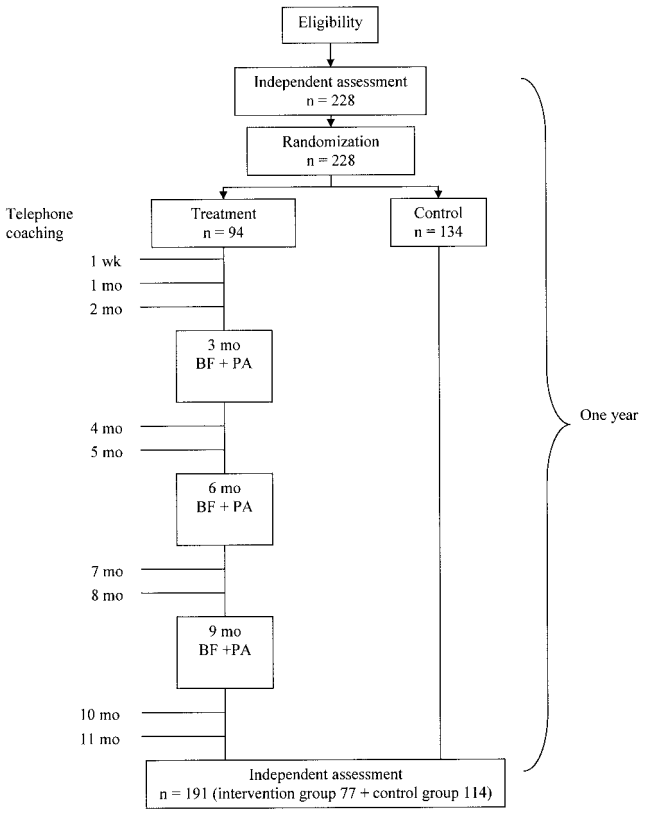

Figure 1. Flow chart of the study design. BF = tests of body functions; PA = self-assessed physical activity.

Participants. A total of 228 patients (169 women, 59 men, mean age 55 years, mean time since diagnosis 21 months) with RA (20) were recruited during 2000–2004 from 10 rheumatology clinics at 7 university hospitals and 3 county hospitals, all located in central Sweden and including urban as well as rural catchment areas. The patients were invited to participate 1 year after their inclusion in the Swedish RA register, a national quality register to which every rheumatology clinic in the country reports their recently diagnosed (within 12 months) patients. Enrollment was carried out locally at each participating clinic and was adjusted to local circumstances. At some clinics, patients were informed and asked for participation by mail prior to their scheduled physician visit; at other clinics patients were informed and asked when already at the clinic. Each patient >18 years of age who was able to communicate adequately in Swedish and perform body-function testing was eligible for inclusion, irrespective of disease status or comorbidity. No specific exclusion criteria were applied. The reason was that any individual, including those of older age in whom comorbidities are common, would benefit from physical activity.

All participants gave their informed consent and were allocated at random, individually and without stratification at each participating clinic by the roll of a die, to an intervention group (n = 94) or a control group (n = 134). The local physical therapists/personal coaches generated the allocation sequence and also assigned patients to their groups as described above. The 2 groups were initially comparable as to demographics, disease activity, and per-

centages of participants taking different types of medication (Table 1).

Our sample was one of convenience, as recruitment was part of ordinary clinical work at the participating clinics and many patients were never asked to participate or did not complete the inclusion process for logistic reasons, such as the physiotherapists' working hours, rescheduled physician visits, failing equipment, or their own lack of time or interest. The number of patients who were never asked or failed to complete the inclusion process was not noted. However, our sample of 228 patients compared well with the rest of the patients with RA included in the RA register (n = 910) at their 1-year controls after diagnosis at the 10 participating clinics during the same period (2000–2004). Therefore, there were no significant differences between the 2 samples as to sex proportions, disease activity (Disease Activity Score in 28 joints [DAS28]), pain, or activity limitation (Health Assessment Questionnaire [HAQ] disability index), but our patients were significantly younger (mean age 55 years versus 60 years; $P < 0.001$) and had a significantly longer disease duration (mean disease duration 21 months versus 18 months; $P < 0.001$).

Table 1. Demographic, disease activity, and medication data at preintervention assessment for 228 participants allocated to intervention or control groups*

	Intervention (n = 94)	Control (n = 134)
Sex, no. (%)		
Men	26 (28)	33 (25)
Women	68 (72)	101 (75)
Age, mean ± SD years	54 ± 14.0	56 ± 13.9
Time since diagnosis, mean ± SD months†	21 ± 4.5	22 ± 4.4
DAS28 (0–10), mean ± SD score	3.2 ± 1.46	3.3 ± 1.38
Medication, no. (%)		
Analgesics, regularly	6 (6)	8 (6)
NSAIDs	27 (29)	32 (24)
Corticosteroids	21 (22)	40 (30)
DMARDs	88 (94)	123 (92)
Anti-TNFα	7 (7)	7 (5)

* DAS28 = Disease Activity Score in 28 joints; NSAIDs = nonsteroidal antiinflammatory drugs; DMARDs = disease-modifying antirheumatic drugs; anti-TNFα = anti–tumor necrosis factor α.
† Significant at $P = 0.05$.

Intervention. All participants in both groups had access to, but were not specifically encouraged to participate in, ordinary physical therapy treatment including patient education, treatment with physical modalities, and organized exercise a maximum of twice per week.

The participants in the intervention group underwent a 1-year program aimed at implementing healthy physical activity (moderately intensive, 30 minutes/day, ≥4 days/week). They were individually coached by a physical therapist and were informed about the benefits of physical activity. Their thoughts about their body function and possibilities for physical activity were discussed. Goals for their physical activity were formulated and documented according to a structured manual based on the principles of graded activity training (21,22). Perceived obstacles to successful implementation were discussed and problem-solving strategies to help overcome present and future barriers were discussed and documented. Continuous telephone support was given after 1 week and then once monthly by the coach. Tests of body functions (muscle function, joint range of motion, and balance) were performed every third month in order to encourage adherence to the goals of graded activity, and oral and written feedback were given about the test results. Activity logs were completed during the 2 weeks prior to each test occasion in order to form a basis for the physical therapists' understanding of whether their patients' physical activity goals were reached. Goals were systematically evaluated and adjusted whenever required.

Twenty-three personal coaches (22 women, 1 man, median age 43 years [range 26, 65], median professional experience 17 years [range 0.5, 25], median experience within rheumatology 7 years [range 0.5, 20]) were involved at the 10 participating clinics. At least 1 coach from each participating clinic underwent a 1-day training program aimed at improving knowledge about the study protocol, the definitions, requirements, and benefits of healthy physical activity, and cognitive–behavioral techniques for behavioral change. An experienced psychologist (IJ) specializing in chronic pain and cognitive–behavioral intervention held lectures in cognitive–behavioral theory and measures based on the techniques developed by Fordyce et al (21,23) and stages of change (24). The coaches were also trained to support participants in setting goals for their physical activity following the principles of graded activity, to identify present and future obstacles to regular physical activity, and to identify strategies for overcoming these obstacles (25,26). Written manuals and forms were used to standardize the coaching process. One recall session was held by the psychologist after 6 months and regular recall sessions on the study protocol were then held by the senior investigator (CHO) once or twice yearly during the entire period of patient inclusion.

Assessments. All assessments used in the study have been developed and/or validated to some extent for use in patients with RA. The assessments were performed pre- and postintervention by independent assessors, physical therapists, and rheumatologists, who were unaware of group assignment.

The EuroQol visual analog scale (VAS) was used as the primary outcome measure. It consists of a 20-cm vertical VAS called a "thermometer," with end points of 100 at the top (best imaginable health state) and 0 at the bottom (worst imaginable health state). The respondent rates his/her current health state by drawing a line from a box marked "your own health state today" to the appropriate point on the EuroQol VAS (27–30).

Two tests of muscle function were used as secondary outcome measures of the study: the Grippit, an electronic device for measuring maximum grip strength in newtons

Table 2. Pre- and postintervention assessment values for primary, secondary, and other outcomes in the intervention group and the control group with baseline values carried forward*

	Preintervention			Postintervention	
	Intervention	Control	*P*	Intervention	Control
EuroQol VAS, 0–100 scale	70 (5, 98)	70 (4, 100)	NS	75 (20, 98)	70.5 (5, 100)
Timed-Stands Test, seconds	21 (8, 43)	20 (10, 46)	NS	17 (8, 42)	20 (9, 76)
Grippit, N	370 (42, 1,083)	308 (24, 1,100)	0.005	439.5 (32, 1,236)	339.5 (20, 1,064)
EPM-ROM, 0–30 scale	4 (0, 13)	4.5 (0, 17)	NS	3.5 (0, 13)	4.5 (0, 15)
Figure-of-8 oversteps, no.	2 (0, 48)	4 (0, 51)	0.007	1.5 (0, 35)	3 (0, 51)
VAS for pain, 0–100 scale	23 (0, 93)	22 (0, 98)	NS	23 (0, 93)	25.5 (0, 98)
HAQ DI, 0–3 scale	0.5 (0, 2.25)	0.5 (0, 2.50)	NS	0.5 (0, 2)	0.5 (0, 2.5)

* Values are the median (range) unless otherwise indicated. VAS = visual analog scale; NS = not significant; EPM-ROM = Escola Paulista de Medicina Range of Motion; HAQ DI = Health Assessment Questionnaire disability index.

(31), and the Timed-Stands Test, which assesses lower-extremity function in seconds (32,33).

Additional outcome measures were the Escola Paulista de Medicina Range of Motion scale to assess general range of joint motion (0–30, where 0 = motion with no restrictions) (34), walking in a figure-of-8 to assess balance by counting the number of oversteps (35), a VAS rating pain (0–100, where a higher score indicates more pain), and the HAQ disability index to assess activity limitation (0–3, where a higher score indicates more activity limitation) (36,37).

Data on physical activity were collected in order to describe the preintervention state and adherence to the intervention. A self-reported questionnaire designed for the present study and including 3 questions on the frequency of low-, moderate-, and high-intensity activity was filled out by each participant. The answer alternatives were never/occasionally, 1–3 times/week, 4–5 times/week, and 6–7 times/week. Test–retest reliability was investigated within the present study and results revealed a weighted kappa coefficient of 0.84 for 2 sets of measurements over 1 week in a convenience sample of 31 patients with RA. The answers to the 3 questions were used to classify participants' physical activity as none (never/occasionally only), low (low intensity only), intermediate (low intensity plus 1–3 times/week of moderate and/or high intensity), or healthy (≥4 times/week of moderate and/or high intensity). In addition, physical therapists using personal knowledge of the intervention group participants acquired during the 1-year intervention rated their degree of goal achievement as 0–25%, 26–50%, 51–75%, or 76–100%.

The DAS28 (0–10 scale) (38) and registration of medication prescriptions were used to monitor their potential covariation with the outcomes. The DAS28 is based on the erythrocyte sedimentation rate (mm/hour), the number of swollen (n = 28) and tender (n = 28) joints, and the patient's self-reported general health perception (VAS, 0–100 mm). Medication prescription was classified as a regular intake of analgesics, nonsteroidal antiinflammatory drugs, corticosteroids, disease-modifying antirheumatic drugs, or tumor necrosis factor α.

Statistical procedures. Between-group analyses were performed with the chi-square test (nominal data), the Mann-Whitney U test (ordinal data), or the Student's *t*-test. Data were analyzed on the basis of intention-to-treat with baseline values carried forward for all those randomized, as well as separately for those who completed the study. A power analysis based on the assumption that 40% of the intervention group participants would improve their health state (>15 mm) while only 20% of the control group participants would do so indicated that 91 participants per group would confer conclusive results ($\beta = 0.2$, $\alpha = 0.05$). The EuroQol might be considered an ordinal scale and therefore, changes cannot actually be quantified. However, a change of <15 units probably reflects a measurement error rather than a true change (39).

Ethics approval. The study design was approved by the regional research ethics committee at Karolinska Institutet.

RESULTS

At preintervention, the intervention group and the control group were comparable on all assessed variables except grip strength and balance, where the intervention group performed better (Table 2). Seventy-seven (82%) participants in the intervention group and 114 (85%) in the control group completed the study. There were no statistically significant differences in any variables in the preintervention assessments between the dropouts and their group peers. Of the 77 intervention group participants who completed the intervention, the physical therapists rated goal attainment as 0–25% for 2 participants, 26–50% for 5, 51–75% for 19, and 76–100% for 42, while 9 were never rated.

There were no differences in reaching healthy physical activity between the 2 groups at either pre- or postintervention assessment (Table 3). Twenty-six (28%) intervention group participants and 23 (17%) control group participants increased their physical activity from no/low or intermediate to any of the higher levels (baseline values carried forward; $P > 0.05$). Of those who completed the study, 26 (34%) intervention group participants and 23 (20%) control group participants increased their physical activity (study completed; $P = 0.035$). Nineteen (20%) intervention group participants and 31 (23%) control group participants decreased their physical activity (base-

Table 3. Physical activity at pre- and postintervention assessment in the intervention group and the control group with baseline values carried forward and study completed

	Healthy physical activity, %
Preintervention	
Intervention	47
Control	51
Postintervention, baseline values carried forward	
Intervention	54
Control	44
Postintervention, study completed	
Intervention	51
Control	42

line values carried forward; $P > 0.05$), and for those who completed the study, 19 (25%) intervention group participants and 31 (27%) control group participants decreased their physical activity (study completed; $P > 0.05$).

Analyses of outcome variables indicated improvements in the intervention group compared with the control group in perceived health status and muscle strength, but not in any of the other variables assessed. Results were similar whether analyzed with baseline values carried forward or for only those who completed the study (Table 4). Twenty-three (24%) participants in the intervention group and 20 (15%) in the control group increased their perceived health status by >15 units (baseline values carried forward; $P > 0.05$). Corresponding figures for only those who completed the study were 23 (30%) in the intervention group and 20 (18%) in the control group (study completed; $P > 0.05$).

Disease activity remained stable (baseline values carried forward), with mean ± SD DAS28 score differences between postintervention and preintervention of −0.12 ± 1.09 in the intervention group and 0.05 ± 1.03 in the control group ($P > 0.05$). The percentages of participants taking different types of medication were comparable between the 2 groups at postintervention ($P > 0.05$).

DISCUSSION

To our knowledge, this is the first study to indicate improvements related to perceived health status and muscle function following a physical activity intervention in patients with RA. A positive outcome related to well being was in line with our hypotheses for the study, as it is the main target of healthy physical activity. The improvement in muscle function as a result of unspecific physical activity was not surprising either, as this is a well-documented effect of moderate exercise (8).

The transferability of the present results is probably high, as the study was carried out in everyday practice at a number of clinics and ordinary physical therapists acted as coaches after a short training program. Furthermore, we think that the physical therapists' training program and the written material used in the study were sufficient to result in behavior changes among the participants, because similar strategies have been used in previous studies with good outcomes (22,40,41). Because data collection took longer than expected, there might have been dilution effects due to staff turnover, new coaches not undergoing formal training, and not all coaches participating in the regular voluntary recall sessions.

We did not find significant differences between the 2 groups in self-reported healthy physical activity after the intervention. The most pessimistic explanation of the positive outcome would therefore be that attention from the physical therapists in combination with the repeated body-function testing and subsequent learning effects caused the improvements in the intervention group. However, the physical therapists' ratings of 90% of the participants as >50% adherent to the goals for healthy physical activity indicates alternative explanations. One explanation relates to the participants' understanding of the physical activity questions. Our impression was that some participants seemed to have a poor understanding, maybe due to limited experience, of moderate- and high-intensity physical activity. This might have paradoxically caused intervention group participants to score lower intensity of physical activity after the intervention and their hands-on acquaintance with the requirements, while many control group participants still remained convinced that their

Table 4. Outcome differences between postintervention assessment and preintervention assessment for the intervention group and the control group*

	Baseline values carried forward			Study completed		
	Intervention (n = 94)	Control (n = 134)	*P*	Intervention (n = 77)	Control (n = 114)	*P*
EuroQol VAS, 0–100 scale	5 (−54, 62)	0 (−69, 81.5)	0.027	7 (−54, 62)	0 (−69, 81.5)	0.02
Timed-Stands Test, seconds	−3 (−21, 5)	0 (−20, 16)	0.000	−4 (−21, 5)	−1 (−20, 16)	0.00
Grippit, N	32 (−292, 320)	0 (−461, 372)	0.003	71.5 (−292, 320)	13.5 (−461, 372)	0.00
EPM-ROM, 0–30 scale	0 (−8, 5.5)	0 (−12.5, 6.5)	NS	−0.5 (−8, 5.5)	0 (−12.5, 6.5)	NS
Figure-of-8 oversteps, no.	0 (−23, 13)	0 (−24, 11)	NS	0 (−23, 13)	−1 (−24, 11)	NS
VAS for pain, 0–100 scale	0 (−78, 70)	0 (−66, 73)	NS	−2 (−78, 70)	0 (−66, 73)	NS
HAQ DI, 0–3 scale	0 (−1, 1)	0 (−1.25, 1.13)	NS	0 (−1, 1)	0 (−1.25, 1.13)	NS

* Values are the median (range) unless otherwise indicated. VAS = visual analog scale; EPM-ROM = Escola Paulista de Medicina Range of Motion; NS = not significant; HAQ DI = Health Assessment Questionnaire disability index.

physical activity was intensive enough to satisfy the requirements. Another explanation might also be that the participants coached by physical therapists performed physical activity of higher quality, resulting in improved muscle functioning despite reporting the same amount and intensity of physical activity as their peers in the control group.

The 2 groups differed in grip strength and balance on preintervention assessment, which might be presumed to have played a part in the positive outcome. This could have been analyzed with multivariate methods. However, for grip strength or balance we found no statistically significant correlations between baseline values or changes during the intervention and the improvement in perceived health status (data not shown). Therefore, we decided not to apply multivariate analyses. For the same reason (lack of correlation to improvement in outcome), we did not believe that age or sex acted as confounders.

As to external validity, our results can definitely be considered valid for patients with early RA treated by specialized rheumatologists. Furthermore, our convenience sample was fairly representative. Therefore, there were no significant differences as to sex proportions, disease activity, pain, or activity limitation between our participants and the rest of the patients who saw their rheumatologist for a 1-year checkup at the clinics involved. However, as might be expected, our participants were younger than their peers. Perhaps those who volunteered for the study were also generally more interested in their health. This is probably something that our study population has in common with patients who accept enrollment in clinical physical activity intervention programs. It probably does not limit the external validity of our results.

Considering our positive outcomes, we think it is important that rheumatologists and physical therapists initiate physical activity interventions in order to improve perceived health status. Furthermore, it is important that physical therapists are trained to support and evaluate their patients' physical activity in a structured manner. Exploration of patients' understanding of exercise and physical activity at different intensities is an important area for further research in order to improve self reports of physical activity in future epidemiologic studies. Unless such work is done, it will be hard to describe the mechanisms underlying the positive outcome of interventions such as the one investigated in our study. Another important area for future research relates to the long-term maintenance of healthy physical activity behavior. Therefore, a followup of the present participants will be performed and reported later.

In conclusion, the 1-year support program for healthy physical activity resulted in improved perceived health status and increased muscle strength among patients with early RA. However, the underlying mechanisms remain unclear, as self-reported healthy physical activity did not increase. This might be partly attributed to assessment difficulties and the patients' poor understanding of the requirements for moderate and intensive physical activity, which should be further explored.

AUTHOR CONTRIBUTIONS

Ms Brodin had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design. Eurenius, Jensen, Nisell, Opava.
Acquisition of data. Brodin, Eurenius, Opava.
Analysis and interpretation of data. Brodin, Opava.
Manuscript preparation. Brodin, Eurenius, Jensen, Opava.
Statistical analysis. Brodin, Opava.

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